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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,077	02/19/2004	Sylvie Demay	069208.0118	4531

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EXAMINER

ROY, ANURADHA

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/782,077	Applicant(s) DEMAY ET AL.	
	Examiner Anuradha Roy	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 7, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-13, 15, & 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restrictions

During a telephone conversation with Paul Morico on December 20, 2005 a provisional election was made with traverse to prosecute the invention of Species I, claims 1-9, 14, & 16, drawn to Figure 1a. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-13, 15, & 17-19 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

Claims 1, 2, 3, 4, & 6 are provisionally rejected on the ground of nonstatutory double patenting over claims 1 & 15, 2 & 16, 14, 4 & 21, & 3, respectively of copending Application No. 2004/0106890. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a system for collection of biological samples, including a collection device, collection bag, sampling device, and a

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first and second tube in the system in order to establish fluid communication the aforementioned components.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 4, 5, 6, & 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathias et al. (US Patent No. 6,387,086).

Regarding claim 1, Mathias et al. discloses a bag system for collecting a biological fluid comprising:

a collection device (element 10 excluding element 18);

a fluid collection bag (16) in fluid communication with the collection device;

and a sampling device (18) in fluid communication with the collection device, the sampling device including: at least one sampling receptacle;

and a transfer device (68 & Figure 4D) having an associating (68, 98, & 100) device operable to support the receptacle in a standby position, guide the receptacle to a transfer position, and allow dissociation of the receptacle from the bag system.

Regarding claim 2, Mathias et al. discloses a system, wherein the biological fluid comprises blood (Abstract).

In regard to claim 3, Mathias et al. discloses a system further comprising: a first tube (15) to establish fluid communication between the collection device and the fluid collection bag; and a second tube (62) to establish fluid communication between the collection device and the sampling device.

With regard to claim 4, Mathias et al. discloses a system, wherein the sampling device (18) further comprises a sampling bag (42) connected to the downstream end of the second tube.

Regarding claim 5, Mathias et al. discloses a system, wherein the receptacle (70) has a body having a first diameter and further comprises a closure element (84) having a second diameter greater than the first diameter

In regard to claim 6, Mathias et al. discloses a system, wherein the transfer device further comprises: a hollow guide (68) open at a front part to allow introduction of the sampling receptacle; and a hollow needle (74 & Column 6, lines 52-55) in fluid communication with the bag system, wherein the hollow needle passes through a rear part of the guide so that a downstream part of the needle extends inside the guide and an upstream part of the needle extends outside the guide (Figure 4B), and wherein the hollow needle is operable to perforate the closure element of the receptacle, placing the downstream part of the needle inside the receptacle (Figure 4B).

With regard to claim 14, Mathias et al. discloses a system, wherein the guide further comprises a cap having a tamper-evident element (17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought

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to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, & 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathias et al. in view of Flumene et al. (US Patent No. 5,364,360).

Mathias discloses an association device (68) having a set of projections (98 & 100), wherein the projections are arranged so as to be deformable by sliding the receptacle inside the guide, and wherein the projections are arranged so as to permit a reversible association of the receptacle inside the guide and the sliding of the receptacle inside the guide between a standby position at a distance from the needle and the transfer position (Figure 4C & 4B). Examiner contends the receptacle (70) is removed, thus the projections (98 & 100) are capable of permitting a reversible association. Mathias, however, does not disclose a second set of projections. However, Flumene et al. discloses two sets of projections (12 & 13), wherein at least one flexible projection (13 & Column 6, lines 66-67) reversibly deformable. Additionally, Flumene et al. discloses the first set of projections breakable under the deformation and located near the needle (Column 6, lines 63-65). It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Flumene et al. to incorporate two sets of projections with Mathias in order to insure correctly positioning the receptacle.

Additional Claim Rejections - 35 USC § 103

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathias et al. in view of Ishida (US Patent No. 5,125,920).

Mathias discloses a blood collection apparatus, but fails to disclose a collection bag and receptacle with at least two identification tags. However, Ishida discloses a identification tags disposed on the collection bag (25) and disposed on the receptacle (26 & 27 & Column 5, lines 16-23), wherein the tags allows the establishment, after their dissociation, that both the collection bag and receptacle originated from the same bag system (Column 5, lines 37-39). It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Ishida to incorporate identification tags on the collection bag and receptacle with Mathias et al. in order to avoid misidentification of the blood for safety purposes.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Maithias et al. (US Patent No. 6,520,948 & US Publication No. 2002/0019621) further discloses a sampling device and holder.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-


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6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~


MAX F. HINDENBURG
SENIOR PATENT EXAMINER
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